Beacon Care Package for Prostate Instructions for Use

Varian Medical Systems
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INTRODUCTION

Before implanting the Beacon® transponders contained in this Beacon Care Package, complete the Calypso® training program and carefully read all sections in this document. This document describes the Beacon Care Package components, implantation procedure instructions, and transponder placement in the prostate.

Each patient should be evaluated to determine if the patient is a candidate for implantation, including whether their size limits them to setup for treatment or setup and tracking during treatment. This must be evaluated prior to Beacon transponder implant, following the guidelines outlined in the *Calypso System User's Manual*.

PRODUCT DESCRIPTION

Beacon transponders are small, passive, electrical components encapsulated in biocompatible glass, which are permanently implanted in or near the treatment target for use during radiation therapy. Beacon transponders were developed specifically for use with the Calypso System in order to provide a reliable and accurate method for target localization and continuous, real-time tracking during radiation therapy treatments. The Calypso System temporarily excites the implanted Beacon transponders; each Beacon transponder then briefly emits a unique response signal, which is detected, measured, and used to determine the location of the patient's treatment target. The Calypso System works in tandem with implanted Beacon transponders to continuously report the current position of the target relative to the treatment isocenter.

This Beacon Care Package contains three single-use 14-gauge introducer needles (introducers) and Beacon transponders for implantation into a single patient. Each transponder is manually loaded into the introducer for implantation.

INDICATIONS FOR USE

The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Implanted Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon transponders are indicated for implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed) to align and monitor the treatment isocenter in real time during radiation therapy.

CONTRAINDICATIONS

- Prosthetic implants in the pelvic region that contain metal or conductive materials (e.g., an artificial hip).
- Use of anti-coagulants or anti-platelet drug therapy (not including aspirin).

WARNINGS

- The effect of the Calypso System operation on active implanted devices, such as pacemakers and defibrillators, in patients is unknown. Be aware that the operation of the Calypso System may impact the normal functioning of such active implanted devices.
- Beacon Care Packages are gamma sterilized and are supplied sterile and non-pyrogenic. Use standard operating procedures to maintain the sterility of the devices during unpacking and use. Do not use if package has previously been opened or appears to be damaged.
- Beacon transponders and introducers are for single use only. Do not re-sterilize or reuse.
- Each Beacon transponder has unique characteristics and should be implanted in the recommended region of the prostate. The introducers are uniquely labeled and color coded to indicate the implant region.
- Beacon transponders must be implanted using transrectal ultrasound imaging for guidance.
- In the event that a Beacon transponder should drop onto the sterile drape during handling, use only a gloved hand to pick up the transponder and place it in the hub end of the introducer; do not use metal tweezers to pick up the transponder as it may damage the transponder surface. If you must use metal tweezers to pick up the transponder, discard the transponder. If the transponder drops on a non-sterile surface, do not use the transponder.
- In the event that an introducer is damaged prior to use, do not use the introducer for implant and dispose of it properly.
- Implantation through a transperineal approach has not been evaluated.

PRECAUTIONS

- Always follow the ultrasound transducer manufacturer's instructions when preparing the transducer to be used in an implant procedure.
- Non-clinical testing has demonstrated that Beacon transponders are MR conditional. A patient implanted with Beacon transponders can be safely scanned under the following conditions:
  - Static magnetic field of 1.5T or 3T;
  - Static magnetic field gradient of 2.5T/m;
  - Maximum whole-body-averaged specific absorption rate of 2.0 W/kg for 20 minutes, in the normal operating mode of MR scanning

  MR artifacts may extend up to, and in some cases more than, 2 cm from the transponder for a spin echo sequence.
- Use caution when the following additional therapies are required in the prostate: brachytherapy treatment (permanent seeds or HDR), electrosurgical procedures (e.g., harmonic scalpel, transurethral needle ablation, radio frequency (RF) ablation), cryoablation, lithotripsy, and laser vaporization. Avoid direct contact with the transponders when administering these therapies. Beacon transponder functionality and encapsulation after administration of these therapies has not been assessed.
- Beacon transponders should be implanted only by physicians who have received Calypso implant training.
- Beacon Care Packages should be implanted before the sterilization expiration date on the package.
- Beacon Care Packages should be stored at standard room temperature (greater than -18 degrees C and less than 55 degrees C) and kept dry.
- Beacon Care Packages contain introducer needles. Handle introducers according to departmental sharps protocols.

COMPONENT DESCRIPTION

Beacon Transponders

Each Beacon transponder consists of a sealed, biocompatible glass capsule containing a miniature passive electrical circuit (Figure 1). The Beacon transponders are visible on kilovoltage radiographs, CTs, and ultrasound images. Each Beacon transponder is packaged in a transfer capsule (Figure 2). The transfer capsule is color coded and labeled A, L, or R to indicate the implant site for the Beacon transponder (Apex, Left mid-gland or base, Right mid-gland or base). The transfer capsule is used to load the Beacon transponder into the introducer.

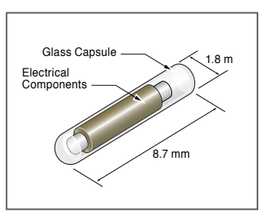


Figure 1

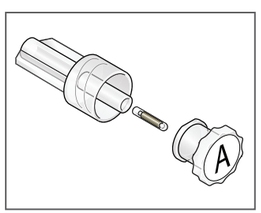


Figure 2

Introducers

- A separate introducer is used to implant each Beacon transponder into a region in or near the treatment target. Each introducer consists of a customized, 14-gauge needle assembly and an internal removable stylet. A color mark on the hub indicates where the distal tip of the needle bevel is located.
- Each pouch contains one introducer and one Beacon transponder. The Beacon transponder must be loaded into the introducer prior to implant (see the section titled "Preparing the Introducers for Implantation" for complete instructions).
- A clip secures the extended stylet to the needle hub (see Figure 3). The clip should be reattached after the Beacon transponder is loaded in the introducer and should be left in place until the time of implant to prevent accidental premature deployment of the Beacon transponder.

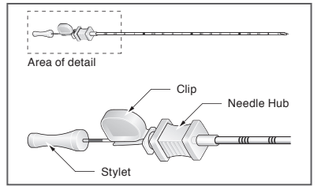


Figure 3

- Each Beacon transponder has a unique frequency associated with a specific region of the treatment target (A, L, and R). The introducer stylets and hubs are color coded (blue, white, and green) to distinguish them (see Figure 4).

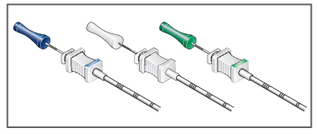


Figure 4

Color	Implantation Position in Prostate
White	Apex
Blue	Left mid-gland or base
Green	Right mid-gland or base

PREPARING THE INTRODUCERS FOR IMPLANTATION

Each Beacon Care Package consists of three pouches. Each pouch contains one introducer and one Beacon transponder packaged in a Beacon transponder transfer capsule. Open one pouch at a time to ensure the correct Beacon transponder is loaded in the corresponding introducer.

To load the Beacon transponder into the introducer:

1. Place a sterile drape on a flat surface.
2. Remove the transfer capsule and introducer from the pouch.
3. Remove the stylet from the introducer, leaving the clip attached to the stylet, and place both the stylet and the introducer on the sterile drape.
4. Hold the transfer capsule upright and unscrew the cap from the transfer capsule, making sure that the Beacon transponder does not fall out of the capsule (see Figure 5).
5. Continue to hold the transfer capsule upright and screw the hub of the introducer needle onto the transfer capsule (see Figure 6). This should be a snug not tight fit.
6. Turn the introducer tip downward so that the Beacon transponder drops into the end of the introducer. If the transponder does not drop on its own, gently tapping the center of the capsule with your finger will cause the transponder to drop into the introducer (see Figure 7). A slight crimp in the end of the introducer prevents the Beacon transponder from falling out.

Figure 5

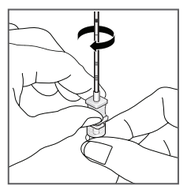


Figure 6

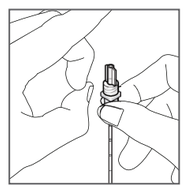


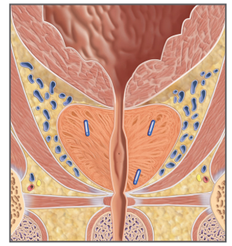
Figure 7

7. Holding the introducer tip pointed downward, unscrew the transfer capsule from the introducer hub.
8. Ensure the clip is attached to the stylet before reinserting the stylet into the introducer.
9. Continue to hold the introducer pointed downward and slowly insert the stylet into the introducer until the clip securely anchors the stylet, being careful not to accidentally advance the Beacon transponder out of the needle.
10. Place the loaded introducer on the sterile drape and repeat this procedure for the remaining introducers.

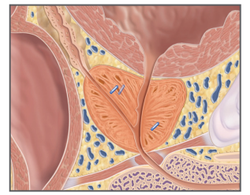
IMPLANT SITE RECOMMENDATIONS

Using transrectal ultrasound imaging, determine the optimal target implant sites for each of the 3 Beacon transponders before beginning the implantation procedure. It is important to consider the following criteria when selecting target implant sites for the Beacon transponders to ensure optimal localization accuracy:

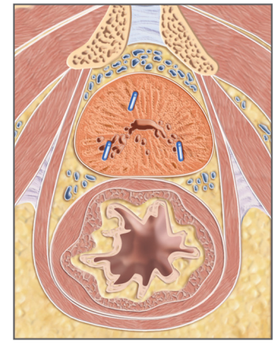
- Each Beacon transponder has unique characteristics, and the individual Beacon transponders are to be placed in the regions of the prostate indicated by the label and color coding of the introducer.
- Implant the Beacon transponders so that the transponders will be equidistant to the midpoint of the prostate.
- Implant the transponders such that they are well within the prostate.
- Avoid implanting the transponders near the urethra.
- The recommended distance between the transponders is 1 cm. If the prostate is too small to accommodate this spacing, select target implant sites within the prostate so that the Beacon transponders will be as far apart from each other as possible (refer to Figure 8).



A: Anterior/Posterior View



B: Sagittal View (Right)



C: Transverse View

Figure 8: Optimal Transponder Implantation Locations

TRANSPONDER IMPLANTATION INSTRUCTIONS

Patient Preparation Prior to Day of Implantation

Per institutional guidelines, consider antibiotic prophylaxis for fiducial implantation of the prostatic bed and use of local anesthesia.

Preparation on Day of Implantation

- Have the patient perform routine bowel preparation to enable transrectal ultrasound (TRUS) imaging prior to the procedure.
- Load the Beacon transponders into the introducers and place them on a sterile drape prior to patient arrival as described in the "Preparing the Introducers for Implantation" section of this document.
- Prepare the patient for transrectal ultrasound (TRUS) examination.
- Ensure that the patient and a sterile field have been prepared for placement of the introducers, as is normally done for a gold marker fiducial implantation or prostate biopsy procedure.
- If necessary, attach a sterile needle guide that will accommodate the 14-gauge introducers to the transrectal ultrasound probe.

Identify Target Implant Sites

11. Insert the transrectal ultrasound probe.
12. Per institutional guidelines, administer local anesthetics early in the procedure to provide time to take effect.
13. Perform the TRUS study of prostate. Using both sagittal and transverse TRUS planes, survey the prostate and obtain a pre-implant prostate volume to ensure adequate size for implantation (10 cc minimum volume recommended).
14. Determine the optimal three target implant sites well within the prostate in the Apex, Left mid-gland or base, and Right mid-gland or base regions of the prostate (refer to Figure 8).
15. Select target implant sites to ensure best use with the Calypso System (see Figure 8).

Prepare and Insert First Introducer

16. Select the appropriate introducer device for the first target implant site (e.g., Apex, Left mid-gland or base, Right mid-gland or base), as indicated by the label and color of the introducer's clip and stylet.

Color	Implantation Position in Prostate
White	Apex
Blue	Left mid-gland or base
Green	Right mid-gland or base

17. Remove the protective plastic sheath from the introducer, but leave the clip in place until the introducer is positioned within the prostate to prevent premature deployment of the Beacon transponder. Insert the introducer into the needle guide.

18. While holding the ultrasound transducer still, position the introducer needle within the prostate so that the tip of the needle is positioned at the first target implant site and the entire beveled tip of the needle is within the prostate

In the ultrasound image, the needle bevel may be seen at the end of two bright parallel lines (refer to Figure 9). If two bright lines are not visible, the needle bevel may be seen as two bright points representing the proximal and distal tips of the bevel.

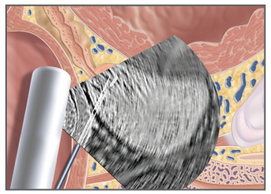


Figure 9

19. When attempting to insert the needle into the prostate, the prostate tissue may resist and become indented around the needle tip (a phenomenon called "tenting," see Figure 10B). To relieve the tenting and ensure the needle tip is completely within the prostate, push the needle tip slightly farther into the prostate, toward the anterior prostate border when viewed on the ultrasound image (Figure 10C), and then withdraw the needle slightly until the prostate returns to its original shape to view the actual insertion depth of the needle tip. Return the distal point of the needle tip to the target site location (Figure10D).

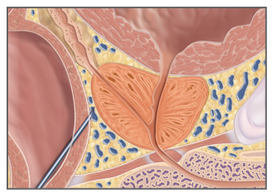


Figure 10 A

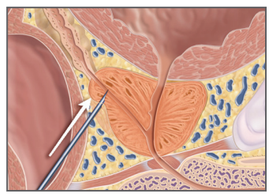


Figure 10 B

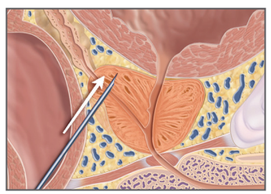


Figure 10 C

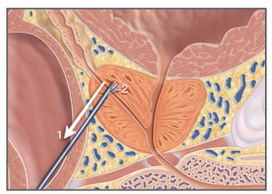


Figure 10 D

The entire beveled tip of the introducer needle must be completely inside the prostate gland prior to deployment of the Beacon transponder. If either the proximal end (Figure 11A), or the distal end (Figure 11B), of the needle tip bevel is positioned outside the prostate when the Beacon transponder is deployed, it is possible that the transponder could be implanted outside the prostate.

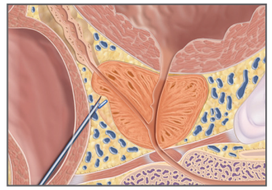


Figure 11 A

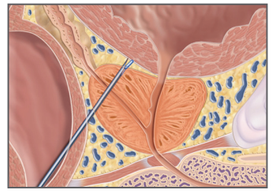


Figure 11 B

Incorrect Transponder Placement

Deploy the Beacon Transponder

20. Remove the clip from the introducer. Once the clip has been removed, hold the introducer hub until the needle tip is positioned at the target site to prevent premature deployment of the Beacon transponder.

21. While continuously holding the introducer in a stable position, so that the tip remains stationary at the target site, gently but steadily push the stylet forward while slightly retracting the cannula (Figure 12) until the Beacon transponder is completely released from the introducer and seen on the ultrasound image.

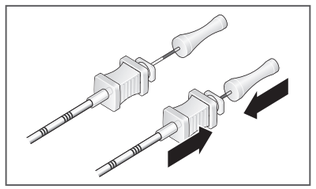


Figure 12

Dispose of Used Introducer Needle

22. Withdraw the introducer needle. Dispose of the used introducer needle in an appropriate sharps biohazard waste container.

Implant Remaining Beacon Transponders

Repeat steps 16 through 22 to implant the second and third Beacon transponders using the appropriate introducer for each implant region of the prostate.

After-Implantation Procedure

- Survey the prostate with TRUS and locate the Beacon transponders.
- Follow standard practice for subsequent patient care following fiducial implantation or biopsy of the prostate.
- Instruct the patient on post-operative care and potential complications.
- Wait 4 to 14 days after the implantation procedure to allow the prostate volume and Beacon transponders to stabilize.
- Acquire treatment planning CT images, using either 1.0-mm or 1.5-mm slice spacing throughout the prostate.
- Perform treatment planning for external beam radiation therapy per standard institutional protocol.
- Perform external beam radiation therapy per standard institutional protocol.
- The implanted Beacon transponders can either be used as radiographic markers with kV x-ray imaging or be used with the Calypso System to facilitate and optimize target localization and tracking during radiation therapy. Refer to the *Calypso System User's Manual.*

ADVERSE REACTIONS

Beacon transponders are implanted in the prostatic bed using standard introduction techniques for gold marker implantation and biopsy of the prostate (e.g., transrectal).

The most frequent adverse events include:

- Bleeding (e.g., hematuria, hematospermia, hematochezia)
- Pain (e.g., procedural, anal, perineal, bowel movements, unspecified)
- Dysuria
- Infection (e.g., urinary tract infection)
- Fever

Other observed adverse events include:

- Urinary retention
- Urinary obstructive symptoms (e.g., urinary frequency, weak stream, etc.)
- Implant migration

The following adverse events also have been documented in the literature following transrectal biopsy; however, they occur in <1% of patients:

- Nausea or sickness
- Allergic reaction to antibiotic prophylaxis
- Perineal swelling
- Sepsis
- Epididymitis
- Temporary fecal incontinence
- Urethral perforation
- Deep venous thrombosis
- Vascular embolization of the implant (e.g., pulmonary embolism)
- Vasovagal episode
- Cardiac arrhythmia

SYMBOLS AND DESCRIPTIONS

The following symbols are used in association with the Calypso System and Beacon transponders.

Symbol	Description	Symbol	Description
MR	MR conditional		Use by
2 STERILIZE	Do not re-sterilize	LOT	Batch code
	Do not use if package is damaged	STERILE R	Sterile using irradiation
2	Do not reuse	55C/131F -18C/0F	Temperature limitation
	Consult operating instructions	80 % 20	Humidity limitation
	Caution, consult accompanying documents		Keep dry

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